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10/538,913	09/29/2005	Andrea Venturelli	5659	5133

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EXAMINER

NEAL, TIMOTHY J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/538,913

Applicant(s)

VENTURELLI, ANDREA

Examiner

Timothy J. Neal

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/13/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15, 20, 23-29, 31, 40-46, 50-53, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Dang (US 5,935,162).

Regarding claim 1, Dang discloses an expandable endolumenal prosthesis comprising, in the non-expanded configuration, a tubular body (Fig. 1), the tubular body having a porous wall defined by a plurality of interlaced circumferential lines forming a pathway motif or pattern (Fig. 2, item 30), in which at least one line is closed onto itself (Fig. 2; col. 4, lines 41-43), each of the lines extends along an axis (implicit for cylindrical sections as in col. 4, lines 41-43), each of the lines comprises at least one plurality of modules (Fig. 2; col. 4, lines 57-59), each module comprises three lobes, that is, two outer lobes and one inner lobe (inner and outer lobes can be defined arbitrarily in the prior art. Consider the lower left of Fig. 2; going from down to up, three bends define three lobes: The bend open to the left adjacent to the bridge defines an outer lobe, the following bend open to the right defines an inner lobe and the following bend open to the left defines an outer lobe) disposed between the two outer lobes in the

Art Unit: 3731

pathway of the pattern, each lobe comprising one or more curved sections having concavities facing in the same direction, defining an apex of the lobe (Fig. 2), the lobes opening alternately on opposite sides of the pathway of the pattern along the extent of the line (col. 5, lines 29-31), both of the outer lobes of the three lobes being extended by straight outer arms (Fig. 2), the at least one plurality of modules being arranged consecutively so as to have successive outer arms which extend from the outer lobes in substantially opposite directions relative to the pathway of the pattern for two successive modules (Fig. 2), for each module, the distance between the apex of one of the outer lobes and the apex of the inner lobe of the same module is less than the distance between the apex of the same outer lobe and the apex of any outer lobe of an adjoining module (Fig. 2), for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line (Fig. 2), at least one connecting element or bridge is provided between two adjacent lines (Fig. 3, item 50), and in which said bridge connects two faced outer lobes of two adjacent lines, said bridge extends along a longitudinal axis parallel to the longitudinal axis of the tubular body (Fig. 2).

Regarding claim 2, Dang discloses the inner lobe of at least one module being extended by at least one straight inner arm (Fig. 2)

Regarding claim 3, Dang discloses both of the ends of the inner lobe being extended by straight arms (Fig. 2).

Regarding claim 4, Dang discloses at least one of the outer arms extends along an axis which is inclined to the longitudinal axis of the tubular body and is also inclined to the axis of the line to which the module belongs (Fig. 2).

Regarding claim 5, Dang discloses both of the outer arms of the module extend along respective axes which are inclined to the longitudinal axis of the tubular body and are also inclined to the axis of the line to which the module belongs (Fig. 2).

Regarding claim 6, Dang discloses the outer arms of the module extend away from the lobes along converging axes (Fig. 2).

Regarding claim 7, Dang discloses the arms have inclinations substantially close to the direction of the longitudinal axis of the prosthesis when the prosthesis is in the non-expanded configuration (Fig. 2).

Regarding claim 8, Dang discloses the inclination of the arms is selected in a manner such that, when the prosthesis is in the expanded configuration, the arms are arranged substantially close to the direction transverse the longitudinal axis of the prosthesis (Fig. 2).

Regarding claim 9, Dang discloses at least one outer arm of a module is shared with the adjacent module (Fig. 2).

Regarding claim 10, Dang discloses all of the outer arms of each module are shared with adjacent modules (Fig. 2).

Regarding claim 11, Dang discloses the outer arms are of equal extent (Fig. 2).

Regarding claim 12, Dang discloses the inner lobe being extended by two straight inner arms (Fig. 2).

Regarding claim 13, Dang discloses the inner arms are of equal extent (Fig. 2).

Regarding claim 14, Dang discloses the inner lobe is joined to the outer lobes by means of at least one inner arm (Fig. 2).

Regarding claim 15, Dang discloses the inner lobe and the inner arm or arms have an overall extent less than the overall extent of the outer lobes and the respective outer arms (Fig. 2).

Regarding claim 20, Dang discloses at least one module has two inner arms of equal extent (Fig. 2).

Regarding claim 23, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for determining the aperture of the cell which faces it (Fig. 2).

Regarding claim 24, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for arranging the arms substantially parallel to the longitudinal axis of the prosthesis when it is in the non-expanded or clenched configuration (Fig. 2).

Regarding claim 25, Dang discloses at least one module comprises at least one lobe comprising at least one curved section of predefined extent suitable for arranging the arms substantially transverse the longitudinal axis of the prosthesis when it is in the expanded configuration (Fig. 2).

Regarding claim 26, Dang discloses at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation (Fig. 2).

Regarding claim 27, Dang discloses at least one module comprises at least one lobe comprising a plurality of curved sections with concavities having the same orientation and at least one interposed straight section (Fig 2).

Regarding claim 28, Dang discloses the inner lobe is joined directly to one of the outer lobes (Fig. 2).

Regarding claim 29, Dang discloses all of the modules of a line have identical characteristics (Fig. 2).

Regarding claim 31, Dang discloses in at least one line, the same module is repeated along the pathway of the line in a mirror-image arrangement with respect to an axis parallel to the axis of the line (Fig. 2).

Regarding claim 40, Dang discloses at least one module is substantially M-shaped and is arranged so as to have outer arms directed substantially either towards the distal end or towards the proximal end (Fig. 2).

Regarding claim 41, Dang discloses the axis of the line is substantially perpendicular to the longitudinal axis of the tubular body (Fig. 2).

Regarding claim 43, Dang discloses the line axis is straight or circumferential (Fig. 2).

Regarding claim 44, Dang discloses for each line, there is at least one adjacent line which has a motif that is a mirror image of the said line with respect to an axis parallel to the axis of the line (Fig. 2).

Regarding claim 45, Dang discloses at least one connecting element or bridge is provided between two adjacent lines (Fig. 3 Item 50).

Regarding claim 46, Dang discloses the bridge defines the interlacing of the lines (Fig. 2).

Regarding claim 50, Dang discloses a bridge is provided between two adjacent lines, for every five complete lobes of a line (Fig. 2).

Regarding claim 51, Dang discloses along the line, a bridge is provided between two adjacent lines, for every first or second outer lobe having the same orientation (Fig. 3 Item 50).

Regarding claim 52, Dang discloses a bridge is provided for every module of the line (Fig. 2).

Regarding claim 53, Dang discloses between two adjacent lines, a continuous closed pathway is provided, disposed between two bridges defining a cell (Fig. 2).

Regarding claim 57, Dang discloses an expandable endolumenal prosthesis comprising, in the non-expanded configuration: a tubular body extending along a longitudinal axis and having a distal end and a proximal end, the tubular body having a porous wall defined by a plurality of interlaced circumferential pattern lines of which at least one is closed onto itself (Fig. 1), each of the lines extending along an axis (every line extends along an axis), each of the lines comprising at least one series of lobes intercalated by arms, each lobe comprising at least one curved section, each arm constituting a straight section (Fig. 3: the lobes are defined for example between the straight arm 34a and the upper arm of 36a, in the region 36a, between the lower arm 36a and 32a, and the following lobe without reference sign), all of the lobes of the series of lobes opening alternately on opposite sides of the pathway of the pattern, along the

Art Unit: 3731

extent of the line (for example Fig. 2, column 20a), for every four consecutive lobes separated by three arms, one of the arms having a greater extent than the other two arms (Fig. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 22, 32, 33, 35-39, 47-49, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang in view of Callol et al. (US 2002/0183763).

Dang discloses the invention substantially as claimed as stated above.

Dang does not disclose the outer or inner arms have an extent which varies in the modules disposed along the longitudinal axis of the tubular body of the prosthesis; at least one module having a single inner arm; in at least one line, the pathway is interrupted so as to form an opening in the pattern suitable for the passage of an SDS guide wire; the pathway is interrupted to an extent equal to one module; the pathway is interrupted to an extent equal to five lobes; the pathway is interrupted between two connecting bridges between the line and adjoining lines; the pathway is interrupted in two adjacent lines; the bridge comprises a bridge lobe; the bridge comprises two bridge lobes; the bridge comprises three bridge lobes.

Callol et al. teaches the outer or inner arms have an extent which varies in the modules disposed along the longitudinal axis of the tubular body of the prosthesis (Fig. 7A Items 26, 28, and 29); at least one module has a single inner arm (Fig 8 Item 28); the prosthesis comprises lines comprising several pluralities of modules (Fig 7A Item 28 and top line of Item 29); the prosthesis comprises three pluralities of modules (Fig. 7B Item 45, Item 34, and the module directly above Item 34); in at least one line, the pathway is interrupted so as to form an opening in the pattern (Fig. 8 Item 40); the pathway is interrupted to an extent equal to one module (Fig. 8 Item 40); the pathway is interrupted to an extent equal to five lobes (Fig. 8 Item 40); the pathway is interrupted between two connecting bridges between the line and adjoining lines (Fig. 8 Item 40); the pathway is interrupted in two adjacent lines (Fig 8 Item 40); the bridge comprises a bridge lobe (Fig. 21 Item 33); the bridge comprises two bridge lobes (Fig. 21 Item 33); the bridge comprises three bridge lobes (Fig. 21 Item 33); a variation of the cell perimeter is provided along the longitudinal axis of the prosthesis (Fig 7A Item 28).

Regarding claim 18, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s varied extent. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel.

Regarding claim 22, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s single inner arm. Such a modification would allow for the passage of a balloon.

Regarding claim 32, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s pluralities of modules. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel.

Regarding claim 33, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s three pluralities of modules. Such a modification would allow the stent to be placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel.

Regarding claims 35-39, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s interruption. Such a modification would allow for the passage of a balloon.

Regarding claims 47-49, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s bridge lobes. Such a modification would enhance the flexibility of the stent.

Regarding claim 54, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s variation of cell perimeter. Such a modification would allow the stent to be

placed in a bifurcated vessel and cover the main vessel and a portion of the side branch vessel.

Claims 16, 17, 19, 21, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang in view of Fischell et al. (US 6,540,775).

Dang discloses the invention substantially as claimed as stated above.

Dang does not disclose the outer and inner lobes with their outer arms and inner arms, respectively, have a non-uniform extent in a direction transverse the axis of the line; the outer or inner arms have an extent which varies in the modules of the same line; the outer arms of the same module have different extents; at least one module has two inner arms of different extents; in at least one line, two pluralities of modules are provided, alternating with one another so as to provide a series of a module of a first plurality and a module of the second plurality; at least one module has outer lobes that are disposed at different distances from the axis of the line.

Fischell et al. teaches the outer and inner lobes with their outer arms and inner arms, respectively, have a non-uniform extent in a direction transverse the axis of the line (Fig 1 L3); the outer or inner arms have an extent which varies in the modules of the same line (Fig 1 19L and 19M); the outer arms of the same module have different extents (Fig 1 19L and 19M); at least one module has two inner arms of different extents (Fig 1 19S and 19L); in at least one line, two pluralities of modules are provided, alternating with one another so as to provide a series of a module of a first plurality and a module of the second plurality (Fig. 1, one module begins with Item 24MC and ends at

Art Unit: 3731

Item 24MU, the next module begins immediately following Item 24MU and encompasses three lobes); at least one module has outer lobes that are disposed at different distances from the axis of the line (Fig 1 L3).

Regarding claim 16, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Callol et al.'s non-uniform extent. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

Regarding claim 17, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s varied extent. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

Regarding claim 19, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s outer arms. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

Regarding claim 21, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s inner arms. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

Regarding claim 30, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include

Art Unit: 3731

Fischell et al.'s two pluralities of modules. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

Regarding claim 34, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Fischell et al.'s outer lobes. Such a modification would reduce the tendency of flaring outward when the stent is advanced through a curved vessel.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang in view of Moore (US 2002/0065547).

Dang discloses the invention substantially as claimed as stated above.

Dang does not disclose the line axis is inclined to the longitudinal axis at an angle of between 5 degrees and 45 degrees and preferably between 10 and 30 degrees.

Moore teaches the line axis is inclined to the longitudinal axis at an angle of between 5 degrees and 45 degrees and preferably between 10 and 30 degrees (Fig 1 a line forming a pathway motif can be defined by the two points 40 and 15. Its inclination is about 30 degrees).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Moore's angle. Such a modification would give the stent superior flexibility characteristics.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang in view of Ragheb et al. (US 6,299,604).

Dang discloses the invention substantially as claimed as stated above.

Dang does not disclose the prosthesis comprises an external or internal coating; the coating comprises a drug.

Ragheb et al. teaches the prosthesis comprising an external coating (Col 3 Lines 6-18) and the coating comprising a drug (Col 3 Lines 6-18).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Dang's stent to include Ragheb et al.'s drug coating. Such a modification would allow a drug to be applied at the site of injury.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

7/24/06.